

Food and Drug Administration, HHS

§ 886.1190

may include a component for measuring macular integrity.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

[55 FR 48441, Nov. 20, 1990, as amended at 59 FR 63012, Dec. 7, 1994; 66 FR 38810, July 25, 2001; 72 FR 17400, Apr. 9, 2007]

§ 886.1120 Ophthalmic camera.

(a) *Identification*. An ophthalmic camera is an AC-powered device intended to take photographs of the eye and the surrounding area.

(b) *Classification*. Class II.

[55 FR 48441, Nov. 20, 1990]

§ 886.1140 Ophthalmic chair.

(a) *Identification*. An ophthalmic chair is an AC-powered or manual device with adjustable positioning in which a patient is to sit or recline during ophthalmological examination or treatment.

(b) *Classification*. Class I. The AC-powered device and the manual device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The manual device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[55 FR 48441, Nov. 20, 1990, as amended at 59 FR 63012, Dec. 7, 1994; 66 FR 38810, July 25, 2001]

§ 886.1150 Visual acuity chart.

(a) *Identification*. A visual acuity chart is a device that is a chart, such as a Snellen chart with block letters or other symbols in graduated sizes, intended to test visual acuity.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation

in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[52 FR 33355, Sept. 2, 1987, as amended at 53 FR 35603, Sept. 14, 1988; 53 FR 40825, Oct. 18, 1988; 66 FR 38810, July 25, 2001]

§ 886.1160 Color vision plate illuminator.

(a) *Identification*. A color vision plate illuminator is an AC-powered device that is a lamp intended to properly illuminate color vision testing plates. It may include a filter.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

[55 FR 48441, Nov. 20, 1990, as amended at 59 FR 63012, Dec. 7, 1994; 66 FR 38810, July 25, 2001]

§ 886.1170 Color vision tester.

(a) *Identification*. A color vision tester is a device that consists of various colored materials, such as colored yarns or color vision plates (multicolored plates which patients with color vision deficiency would perceive as being of one color), intended to evaluate color vision.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[52 FR 33355, Sept. 2, 1987, as amended at 53 FR 35603, Sept. 14, 1988; 66 FR 38810, July 25, 2001]

§ 886.1190 Distometer.

(a) *Identification*. A distometer is a device intended to measure the distance between the cornea and a corrective lens during refraction to help measure the change of the visual image when a lens is in place.